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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,877	11/20/2003	Hee Kyung Ju	912-42	5636

23117 7590 12/03/2008
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EXAMINER	
HAIDER, SAIRA BANO	
ART UNIT	PAPER NUMBER
1796	
MAIL DATE	DELIVERY MODE
12/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,877	JU ET AL.	
	Examiner	Art Unit	
	SAIRA HAIDER	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,12,13 and 17-19* is/are pending in the application.

4a) Of the above claim(s) *1-9,13,17 and 18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/11/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 12 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathiowitz et al. (WO 00/32307) in view of Asgharian (US 5,672,213).

3. Mathiowitz discloses the preparation of multi-wall polymeric microcapsules from hydrophillic polymers. In the preferred method, two polymers are dissolved in an aqueous solvent, the substance to be incorporated is dispersed or dissolved in the polymer solution, the mixture is suspended in an organic solvent or polymer/water mixture and stirred, and the solvent is slowly evaporated, creating microspheres with an inner core formed by one polymer and an outer layer formed by the second polymer (abstract). Thus resulting in the formation of a hard multi-layered microcapsule.

4. In reference to the substance to be incorporated, i.e. the core material, Mathiowitz discloses suitable examples including biologically active substances, such as enzymes (Page 11, lines 19-23).

5. The reference discloses that a surface active agent can be added into the second solution, suitable examples include emulsifiers (page 11, lines 30-32). Therefore, it is clear that upon mixing of the polymer solution with the substance to be incorporated an emulsion is formed.

6. Mathiowitz exemplifies polyethylene glycol (molecular weight of 8,000 Da) as one of the polymers, thus reading on the claimed high molecular weight polyol. Mathiowitz discloses a variety of suitable polymers usable in the disclosed encapsulation method, wherein the first and second (wall-component) polymers are hydrophillic, water soluble polymers, such as poly(n,n-dimethyl

aminomethacrylate) and poly(hydroxyl ethylmethacrylate). Mathiowitz discloses that the first and second polymers must be immiscible in each other (page 5, line 10 to page 6, line 17).

7. Via exemplification of polyetheylene glycol, the reference prefers it as the first polymer (high molecular weight). It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the above mentioned polyamine or hydroxyl-acrylate as the wall-component polymer given that the claimed polymers are recognized as suitable in the invention. One of ordinary skill in the art would readily recognize, via the guidance of Mathiowitz to utilize polymer which are immiscible in each other, that the disclosed polyamine or hydroxyl-acrylate is immiscible in polyethylene glycol.

8. The Mathiowitz reference teaches all of the claimed limitations with the exception of the dispersion of the enzyme into a low molecular weight polyol, as claimed. Thus, attention is directed towards the Asgharian reference. The Asgharian reference discloses the stabilization of enzymes prior to use in order to obtain maximal activity once the enzyme is put to use (col. 3, lines 6-16). Specifically, the Asgharian reference discloses the use of polyols to aid in the stabilization of the enzyme, suitable examples of polyols include polyethylene glycol 200 (molecular weight of 200) (col. 4, lines 52-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to stabilize the enzyme with a low molecular weight polyol, such as those described by Asgharian, and utilize the stabilized enzyme suspension as the substance to be incorporated in the encapsulation process of Mathiowitz. It is noted that the Mathiowitz discloses that the substance to be incorporated can be provided in a suspension in order to not be adversely affected by the polymer, polymer solvent, or the temperature at which solvent evaporation occurs (Page 11, lines 24-29), thus motivating one to utilize the polyol enzyme stabilizing solution of Asgharian. Further,

motivation for the combination is provided by the fact that stabilization of the enzyme is preferred in order to obtain maximal activity from the enzyme once it is put to use.

9. In reference to the claimed limitations regarding the triple-layered microcapsule, since the prior art teaches the identical chemical compounds formed via the identical process claimed by applicant, the triple-layered structure which applicant claims is necessarily present in the prior art.

10. In reference to the claimed functions of the low and high molecular weight polyols, and the separation of the polyols (newly added limitation of step 4), it is noted that since the polyols, enzymes, and polymers disclosed in the prior art are identical to those claimed and disclosed in applicant's specification, it is inherent that the prior are polyols and emulsion are capable of performing the claimed functions.

11. In reference to claim 12, the Mathiowitz reference fails to disclose the claimed enzymes. However, the Asgharian reference discloses a variety of enzymes, such as alkaline proteases, a type of hydrolase (col. 6, lines 15-20). Wherein it would have been obvious to used alkaline proteases as the enzymes in the method taught by the above combination of references in order to utilize an enzyme which is recognized as ophthalmically acceptable (col. 5, lines 54-65).

Response to Arguments

12. Applicants have argued that the Asgharian reference does not teach using a polyol by itself, rather the reference discloses the inclusion of an aromatic acid derivative in combination with at least one polyol to stabilize and sustain activity of the enzyme. In response it is noted that the claims do not exclude the presence of other components to stabilize the enzyme. Wherein the examiner is not alleging that only the polyol should be utilized, rather the rejection clearly states one would be motivated "to utilize the polyol enzyme stabilizing solution of Asgharian."

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAIRA HAIDER whose telephone number is (571)272-3553. The examiner can normally be reached on Monday-Friday from 10am-6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy P. Gulakowski can be reached on (571) 272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Randy Gulakowski/
Supervisory Patent Examiner, Art Unit 1796

Saira Haider
Examiner
Art Unit 1796